for performing the method, and a method for detecting a mutation in one or more nucleotides.

REMARKS

Claims 1-23 are present in the present application and have been subjected to restriction by the Examiner under PCT Rule 13.1 as follows:

I. Claims 1-18 and 24-32, drawn to a method for detecting a difference of one or more nucleotides, a computer program product for performing the method, and a method for detecting a mutation in one or more nucleotides.

II. Claims 19-21, drawn to an apparatus capable of detecting a difference of one or more nucleotides.

III. Claims 22-23, drawn to a use of MALDI-TOF in the detection of a difference of one or more nucleotides.

The Examiner alleges that the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. More specifically, the Examiner alleges that the inventions of Groups II-III do not require the use of the computer program of Group I.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims 1-18 and 24-32, drawn to a method for detecting a difference of one or more nucleotides, a computer program product for performing the method, and a method for detecting a mutation in one or more nucleotides. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2.

PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." (Emphasis added.)

Applicants submit that Groups I-III represent one single inventive concept warranting examination in a single application. More specifically, the apparatus of Group II is "capable of detecting a difference of one or more nucleotides between a nucleic acid molecule and a reference nucleic acid molecule," i.e., such apparatus carries out the methods of Group I. In addition, as recited in claims 22-23 of Group III, the use of MALDI-TOF ("matrix assisted laser desorption ionization – time of flight mass spectrometer) of Group III is also for the purpose of the detection of a difference of one or more nucleotides between a nucleic acid molecule and a reference nucleic acid molecule. Thus, Groups I-III are clearly interrelated under a single inventive concept: to achieve the detection of a difference of one or more nucleotides between a nucleic acid molecule and a reference nucleic acid molecule by using MALDI-TOF or an equivalent procedure.

In addition, Applicants observe that 37 C.F.R. § 1.475(a) states:

> "Where a group of invention is claimed in an application, unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

It is respectfully submitted that the methods and the computer program product of Group I, the apparatus of Group II and the use of MALDI-TOF of Group III share a special technical feature, i.e., to detect a difference of one or more nucleotides between a nucleic acid molecule and a reference nucleic acid molecule by using MALDI-TOF or an equivalent

procedure, which special feature defines a contribution over the prior art and thus satisfies the requirements for unity of invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

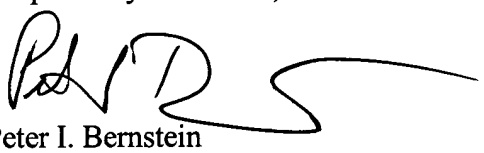
It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is

available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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